

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Patton et al.	Group Art Unit: 3771
Application No: 10/693,318	Examiner: Matter, Kristen Clarette
Confirmation No: 8226	Attorney Docket No: 0001.13 (53207-US-CNT[4])
Filed: October 24, 2003	
Title: METHOD AND DEVICE FOR DELIVERING AEROSOLIZED MEDICAMENTS	July 13, 2009 San Francisco, California 94107

REPLY BRIEF

VIA ELECTRONIC FILING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner:

In response to the Examiner's Answer mailed on May 13, 2009, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby maintains the appeal to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

Certificate of Transmission

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By: Melanie Hitchcock
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Date: July 13, 2009

Status of Claims

Claims 2-39 are presently pending in the case. Claims 2-39 have been finally rejected. The rejection of each of claims 2-39 is hereby appealed.

Claim 1 has been cancelled.

Grounds of Rejection to be Reviewed on Appeal

Appellant continues to request review of the Examiner's following grounds of rejection:

Claims 2, 5-7, 9-11, 14-16, 18-20, 23, 26, 27, 30, 31, 33 and 34 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,522,383 to Calvert et al (hereinafter Calvert et al) in view of U.S. Patent 4,022,224 to Saifer et al (hereinafter Saifer et al). [Note that the Final Office Action states that claims 14-26 are rejected, but Appellant assumes this was a typographical error and 14-16 was intended.]

Claims 3, 12 and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al and Saifer et al, and further in view of U.S. Patent 4,174,712 to Moren et al (hereinafter Moren et al).

Claims 4, 8, 13, 17, 29 and 32 have been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al and Saifer et al, and further in view of U.S. Patent 3,809,084 to Hansen (hereinafter Hansen).

Claims 21, 24, 35-37 and 39 have been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al and Saifer et al, and further in view of U.S. Patent 4,396,152 to Abplanalp (hereinafter Abplanalp).

Claims 22 and 25 have been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al and Saifer et al, and further in view of U.S. Patent 4,860,740 to Kirk et al (hereinafter Kirk et al).

Claim 38 has been rejected under 35 U.S.C. §103(a) as being unpatentable Calvert et al, Saifer et al and Abplanalp and further in view of Hansen.

Argument

Appellant believes each of claims 2-39 are improperly rejected and are therefore allowable for the reasons set forth in Appellant's Appeal Brief filed on March 23, 2009. The present Reply Brief is being filed to specifically address some of the issues raised by the Examiner in the Examiner's Answer mailed on May 13, 2009. The comments herein are merely supplemental to the arguments made in the Appeal Brief and are not meant to replace those arguments.

Characterization of Calvert et al inhaler structure is improper

The Examiner states on page 9 of the Examiner's Answer that "... the structure of Calvert et al. is the same as the instant invention and therefore would be fully capable of delivering the claimed suspension amount." This contention is without merit and without relevance.

First, the Examiner's contention is without merit. The Examiner offers no basis or evidence for proffering that the structure of Calvert et al is the same as the instant invention. Even after a cursory review of Calvert et al and the instant invention, one of ordinary skill in the art would not be lead to believe that the two structures are "the same" and would certainly not find that the two structures would necessarily produce the same aerosolization characteristics.

Secondly, the Examiner's contention is without relevance. Appellant's claim 2, for example, is not to a device structure alone. Instead, in claim 2 Appellant has positively recited a powder medicament comprising a protein or polypeptide. It is the combination of an inhaler structure and powder medicament that must satisfy the claim language. As discussed in the Appeal Brief, prior to Appellant's invention powder medicaments comprising a protein or polypeptide had not been formulated and combined with an inhaler in a way that results in at least 40 percent by weight of the

powder medicament being suspended in a chamber. The Examiner's contention that Calvert et al is "fully capable of delivering the claimed suspension amount" fails to take into account all positively recited limitations claimed by Appellant. The Examiner appears to be following the long-honored patent law rubric that a picture frame can read on a claim to a toilet seat. However, that rubric ceases to apply when the toilet water is being claimed along with the toilet seat. Thus, in the present case, the Examiner's argument simply does not hold water.

The present case is distinguishable from *In re Aller*

The Examiner relies on *In re Aller*, 220 F.2d 454 (1955) for the proposition that one of ordinary skill in the art would arrive at Appellant's invention through routine experimentation. However, the present case is distinguishable from *In re Aller*.

In re Aller applies to situations where general conditions of a claim are disclosed in the prior art. In such cases, *In re Aller* held that it is not inventive to discover the optimal or workable ranges by routine experimentation. In *In re Aller*, the patent applicant took a known process and simply adjusted a process variable to arrive at the same result.

In re Aller is not analogous to the present case. First, the general conditions of Appellant's invention are not disclosed in the prior art. Secondly, there are no process conditions that Appellant is adjusting for optimization. Instead, Appellant has put together an inhaler and a powder in a way that results in an aerosolization efficiency that had never been achieved before. Thus, the present case is clearly distinguishable from and in no way controlled by *In re Aller*.

The present case is also distinguishable from *In re McLaughlin*

The Examiner relies on *In re McLaughlin*, 443 F.2d 1392 (1971) in response to the Appellant's contention that the combination of Calvert et al and Saifer et al is based on impermissible hindsight reasoning. However, the present case is distinguishable from *In re McLaughlin*.

As the Examiner acknowledges, *In re McLaughlin* applies when one takes into account only knowledge which was within the level of ordinary skill at the time the invention was made. The Examiner has made no showing of any such knowledge being present at the time the invention was made. Calvert et al makes no suggestion of the use of powders of the type claimed by Appellant. Saifer et al leads an artisan to a different type of inhaler than the one claimed (see column 5 lines 38-40). The dots being connected by the Examiner are simply not dots that are supplied by the prior art.

Conclusion

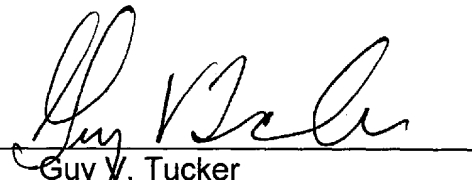
Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments and the arguments provided in the Appeal Brief. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted,

JANAH & ASSOCIATES

Dated: July 13, 2009

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